FLEXIBLE ORGANIZATION OF THE INTERCEPT PATHOGEN INACTIVATION PROCESS FOR PLATELETS OMITS EXTENSION OF PRODUCT SHELF-LIFE

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Problem: In 2011 the blood transfusion service Zurich was one of the first center in Switzerland which introduced the INTERCEPT^{TM} pathogen inactivation (PI) technology for platelet concentrates (PC) into routine. PCs are produced by apheresis (PCA) or by pooling 5 of buffy-coats (PCBC). UVA illumination is performed on 4 days/week (Tue-Fri) during 2 shifts/d. Infectious markers are available at 2pm of d1, while drawing day being d0.
Due to quality concerns, the shelf-life for PI treated PCs was kept at max. 5 days. Therefore several process adaptations were necessary to avoid weekend shifts and stockouts.
Methods: PCAs were scheduled for illumination in the morning of d1 followed by CAD-incubation and release in the afternoon. During PCA illumination PCBCs were produced using OrbiSac System (CaridianBCT), illuminated immediately after PCAs and released in the evening (1st run of PCBCs). A 2nd run of PCBCs was started in the afternoon and products were released on d2. A 2nd run of PCAs was scheduled between 1st and 2nd run of PCBCs, if required.
1 - 2 operators using 2 Illuminators managed 100% of PCs. Throughput, cycle time of PI (CT), CAD incubation time (CAD-t) and product defects during PI as well as PC purchasing due to shortage were assessed. Data were collected by in-house adapted IT-system.
Results: During the first 16 weeks (11/1 - 29/04/2011) 1850 PCAs and 1449 PCBCs were worked up. In average 52 PCs/d with a throughput peak of 108 PCs/d were processed. 81% of PCs were released on d1. Mean CT for PCAs and PCBCs were 6.4h (PCAs), 7.3h (PCBCs, 1st run) and 15.3h (PCBCs, 2nd run), respectively. CAD-t was approx. 1h shorter than CT. No product defects due to PI occurred. 10 PCs (0.3%) needed to be purchased to fulfill hospital requests.
Conclusions: The designed PI work flow runs well and allows to adapt on increasing product needs. No extension of product shelf-life was necessary to comply with irregular hospital demand on products.